

		<b>Oraquick Advance HIV 1/2 Antibody Test</b>	<b>Uni-Gold Recombigen HIV</b>	<b>Clearview Complete HIV 1/2</b>	<b>Determine Combo HIV</b>	<b>Insti HIV-1 Antibody Test*</b>	<b>DPP HIV 1/2 Assay*</b>
Specimen Collection	Venipuncture Whole Blood	YES	YES	YES	YES	YES	YES
	Fingerstick Whole Blood	YES	YES	YES	YES	YES	YES
	Plasma	YES	YES	YES	YES	YES	YES
	Serum	NO	YES	YES	YES	NO	YES
	Oral Fluid	YES	NO	NO	NO	NO	YES
Complexity	Waived	Whole Blood Oral Fluid	Whole Blood	Whole Blood	Fingerstick Whole Blood	Fingerstick Whole Blood	Whole Blood Oral Fluid
	Moderate	Plasma	Plasma Serum	Plasma, Serum	Venipuncture Whole Blood, Plasma, Serum	Venipuncture Whole Blood, Plasma	Plasma, Serum
Shelf Life	Control Kits	12 months unopened 8 weeks opened	12 months unopened 1 month opened	18-24 months opened or unopened	18 months opened or unopened	12 months (freezer) 28 days (refrigerator)	24 months opened or unopened
	Test Kits	30 months	12 months	24 months	15 months	12 months	23 months
Temperature Requirements	Control Storage	2 to 8°C (35 to 46°F)	2 to 8°C (35 to 46°F)	2 to 8°C (35 to 46°F)	2 to 8°C 35 to 46°F	≤ -20 to +8°C (≤ -4F to 46°F)	2 to 8°C (35 to 46°F)
	Test Kit Storage	2 to 27°C (35 to 80°F)	2 to 27°C (35 to 80°F)	8 to 30°C (46 to 86°F)	2 to 30°C (36 to 86°F)	15 to 30°C (59 to 86°F)	2 to 30°C (36 to 86°F)
	Testing Environment	15 to 37°C (59 to 99°F)	15 to 27°C (59 to 80°F)	18 to 30°C (64 to 86°F)	15 to 30°C (59 to 86°F)	15 to 30°C (59 to 86°F)	(18 to 30°C) (64 to 86°F)
Time	Minimum Time for Development	20 minutes	10 minutes	15 minutes	20 minutes	1 minute	Blood: 10 minutes after running buffer Oral: 25 minutes after running buffer
	Read Window	20 minutes	2 minutes	5 minutes	10 minutes	5 minutes	15 minutes

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<b>Sensitivity HIV-1</b> (95% confidence limits)	Venipuncture Whole Blood	99.6%	100%	99.7%	99.9%	99.9%	99.9%
	Fingerstick Whole Blood	99.6%	100%	99.7%	99.9%	99.8%	99.8%
	Plasma	99.6%	100%	99.7%	99.9%	99.9%	99.9%
	Serum	N/A	100%	99.7%	99.9%	N/A	99.9%
	Oral Fluid	99.3%	N/A	N/A	N/A	N/A	98.9%
<b>Specificity</b> (95% confidence limits)	Venipuncture Whole Blood	100%	99.8%	99.9%	99.7%	100%	99.9%
	Fingerstick Whole Blood	100%	99.8%	99.9%	99.8%	99.5%	100%
	Plasma	99.9%	99.8%	99.9%	99.7%	100%	99.9%
	Serum	N/A	99.7%	99.9%	99.6%	N/A	99.9%
	Oral Fluid	99.8%	N/A	N/A	N/A	N/A	99.9%
<b>Detection Time Frame**</b> Days <b>after</b> HIV-1 RNA is detectable (~10 days)		23.7 days	21.6 days	19.7 days		13.5 days	17.5 days
<b>HIV-2 Detection</b>		Yes	Yes	Yes	Yes	No	Yes
<b>Materials Provided in Test Kit</b> (not including manufacturer supplied paperwork)		Test device, developer solution, reusable test stands, specimen collection loops	Test device, wash solution, disposable pipettes, disposable finger- stick sample collection pipettes	Sampler with test strip, buffer vial, sterile safety lancet, bandage, disposable test stands	Test device and cover, chase buffer, disposable capillary tubes, disposable workstations	Test device, 3 solution vials, safety lancet, specimen collection capillary pipette, alcohol swab,	Test device, oral fluid swab, disposable sample loops, SampleTainer bottle, Running Buffer
<b>Available Kit Sizes</b>		100 count 25 count	20 count	25 count	100 count 25 count	24 count 1 count	20 count
<b>Generation of detection</b>		2 <sup>nd</sup> generation lateral-flow	3 <sup>rd</sup> generation lateral-flow	2 <sup>nd</sup> generation lateral-flow	4 <sup>th</sup> generation lateral-flow	2 <sup>nd</sup> generation flow-through	2 <sup>nd</sup> generation dual path platform

\*Not currently provided by North Carolina Communicable Disease Branch as of January 2015.

\*\*Median of 95% confidence intervals representing the estimated ranges of days that HIV-1 tests begin to detect HIV-1 infection AFTER HIV-1 RNA is detectable. The interval between HIV infection and the appearance of HIV-1 RNA is estimates to be around 10 days, but the absolute range is not yet known. See <http://www.cdc.gov/hiv/pdf/testingAdvDisadvHIVtesting62314.pdf> for further details.